

Board of Pharmacy
FINAL STATEMENT OF REASONS

Hearing Date: January 20, 2010

Subject Matter of Proposed Regulation: Patient-Centered Prescription Drug Container Labels

Title 16 Sections Affected: Add § 1707.5.

Updated Information

The Initial Statement of Reasons is included in the file. The information contained therein is updated as follows:

The Board of Pharmacy issued a 15-day Notice of Modified Text on February 22, 2010, to change the minimum font size specified in subdivision (a)(1) from 12-point to 10-point; to change in subdivision (a)(2) the word “may” to “shall” and change “white space” to “blank space”; to amend subdivision (a)(3) to better specify the printing of additional information on the label; to amend subdivision (a)(4)(A) – (Q) to specify that the pharmacist shall insert the appropriate dosage form within standard directions for use, and in subparagraph (P) rephrase standard directions related to paid and include a period of time to wait before taking again; amend subdivision (d) to specify that the pharmacy shall have policies and procedures in place to assist persons with limited or no English proficiency and – at minimum – provide interpretive services in the patient’s language; and add subdivision (f) to define the term “appropriate dosage form.”

The Board of Pharmacy issued a 15-day Notice of Modified Text on April 28, 2010, to add in paragraph (1) of subdivision (a) a requirement that, if requested by the consumer, that the items specified in subparagraphs (A) through (D) be printed in at least 12-point typeface; and strike from subparagraph (D) of paragraph (1) of subdivision (a) the words “or otherwise known to the pharmacy and its inclusion on the label is requested by the patient.” This latter amendment was made to make the language of the regulation consistent with the provision of law that allows the condition or purpose to be placed on the prescription label (see Business and Professions Code section 4076(a)(10)).

To correct a transposition error, Item number 4. of the Underlying Data (p. 4) should read “Senate Bill **472** (Corbett) – Chapter **470**, Statutes of 2007.”

Local Mandate

None.

Business Impact

This action may have an economic impact on small businesses. As reflected in the Economic Impact Statement, the board estimates that the cost to a small business could be as great as

\$1,000. Testimony received during the rulemaking process from a small business (independent pharmacist) indicated his cost may be either \$40 or \$400, depending on the business solution he implements to ensure that his prescription labels conform to the requirements of the regulation. Chain pharmacy industry representatives provided broad comments during the rulemaking process citing “significant costs” and “burdensome” requirements, but did not offer to the board any cost estimates or cost data to quantify their claims of “significant costs.” Public comment from one of the industry representatives that claimed “burdensome” requirements stated at the April 2010 Board Meeting that their member pharmacies would be able to comply with the requirements of the regulation.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the board would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Summary and Response to Objection or Recommendations

The Board of Pharmacy accepted comments during the following public comment periods:

November 20, 2009 – January 4, 2010 – Initial Proposed Text (45-day)
January 20, 2010 – Regulation Hearing, Sacramento
February 22, 2010 – March 10, 2010 – Modified Text (1st 15-day)
April 28, 2010 – May 23, 2010 – Modified Text (2nd 15-day)

Pursuant to Government Code section 11346.9(a) the board has prepared a summary and response to each objection or recommendation specifically directed at the agency’s proposed action [text] or to the procedures followed. Repetitive comments have been summarized and responded to in aggregate.

Comments that do not specifically address the proposed or modified action [text] or address the procedures followed in adopting the action have been summarized in aggregate. Government Code section 11346.9(a)(3) specifies that a comment is “irrelevant” if it is not specifically directed at the agency’s proposed action or to the procedures followed by the agency in proposing or adopting the action.

§1707.5(a)(1) – Percentage of label utilized for specified elements

During the 45-day comment period, the NACDS, CPhA and CRA requested that the board not mandate that certain items occupy 50% of the label.

The NACDS, CPhA and CRA stated that the requirements for a specific type size, use of 50% of the label space, and the specified directions language are unreasonable due to limited label

space. They stated a requirement to use 12-point sans serif for four specified items and to use 50% of the label space for these items is burdensome and unworkable in view of the other information that must be on the label and the limited label space. Ms. Mary Staples, NACDS, testified that designing 50% of the prescription label for four elements is unreasonable and that such a requirement may increase the vial size needed to accommodate a label. The NACDS, CPhA and CRA referred to Business and Professions Code §4076 – requirements for prescription labels, and assert that using only 50% of the label for all other items that need to be printed is not feasible.

Dr. Colenbrander stated in a letter that the board may want to define what is “most important”; what is “important”; and what is “less important” and that such determinations should be based on a study of medication errors where misreading played a role.

At the regulation hearing conducted on January 20, 2010, Mr. Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy (NABP), also indicated that the board’s proposed regulations reflect the analysis prepared by the NABP’s Task Force on Uniform Prescription Labeling.

Board Response

Dr. Colenbrander’s comment somewhat mirrors information provided to the board in October 2009. In an article in the September 2009 issue of Association News entitled “Updated Model Act Addresses Quality and Safety in Patient Care,” a recommendation by the NABP Task Force on Uniform Prescription Labeling Requirements indicated that “critical information for patients” should be set apart (i.e., clustered) on a prescription medication container label. The board utilized a variety of medical literacy research and data (as specified in the Initial Statement of Reasons) and determined that the information in proposed 1707.5(a)(1) does indicate what is most important, and specifies those elements in subparagraphs (A) through (D). The board further determined that the information should be ordered and clustered together on 50-percent of the label to provide an easy-to-understand format and structural safeguards for patients.

The board does not prescribe what size of prescription drug container (i.e., vial, dram, bottle) is to be utilized for prescription drugs. It is within a pharmacist’s scope of practice to determine what size container to use for a given prescription. During many of the SB 472 form meetings, as well as at several Board Meetings, the board viewed actual prescription drug containers and labels. Some pharmacies used small vials for a 30-day supply of a prescription, while other pharmacies used much larger vials for the same supply. The board rejects the assertion that “clustering” the patient-centered items specified in §1707.5(a)(1)(A) – (D) is unreasonable. As reflected in the board’s public protection mandate (Business and Professions Code §4001.1.) “Protection of the public shall be the highest priority for the California State Board of Pharmacy.... Whenever the protection of the public is inconsistent with other interest sought to be promoted, the protection of the public shall be paramount.”

General comments regarding layout of the label

The board received the following comment regarding the layout of the prescription label. The comment is summarized below but is not responded to as it does not address any specific modified text, state objection to the specific modified text or comment on the procedures followed by the board.

Mr. Stephen Laverone states that mandating where items appear on an Rx label may cause pharmacies and software providers to expend large amounts of money. He makes a statement that the requirements for labels is becoming so cumbersome that a label the size of a 3 x 5 card will be needed to get all the information on it. He states that the proposed regulation does not include a route of administration.

1707.5(a)(1) – Font size and type

In response to the proposed text (45-day comment period) and during the regulation hearing held January 20, 2010, the board received multiple comments and testimony/public comment in support of a provision that a patient-centered prescription label be printed in a minimum 12-point (or larger) sans serif font.

At the regulation hearing conducted January 20, 2010, the board heard testimony from proponents of health literacy, health literacy experts, seniors, language access proponents, senior organization representatives and others that a 12-point font – at a minimum – is necessary.

Dr. Michael Wolf, North Western University, and Director of the Center for Communication in Healthcare testified that he has approximately three decades worth of research to support the use of 12-point font, and he cautioned the use of a font size smaller than 12-point. Dr. Wolf and others spoke in support of sans serif fonts. Additionally, Dr. Wolf stated that other fonts support comprehension, which is reflected in the underlying data utilized in this rulemaking. As a member of the U.S. Pharmacopeia Taskforce for drug labeling, he states that USP recommends utilizing 12-point font. Dr. Wolf also testified as to comprehension, and that eye tracking studies clearly show that comprehension can be improved in 12-point font – which has been the standard that has been supported by multiple agencies within NIH. He suggests that there is a precedent for 12-point font that has been longstanding and available throughout health and human services. Dr. Wolf testified his disagreement with requiring only a 10-point font because requiring the critical pieces of information in a larger font makes the label patient-centered, and font size itself can be a cue to help people recognize that information is more important, and that it should stand out amongst other pieces of information, such as a pharmacy logo.

In a letter, Dr. Colenbrander recommends that, rather than requiring a 12-point font for all information, he recommends a standard that allows some variation, depending on the importance of the information – using the Target labels as an example. Dr. Colenbrander stated his support of a sans-serif font.

Dr. Steve Gray, Kaiser Permanente, spoke in support of the concept of an alternative to a 12-point font requirement, but only one that would not reduce the font size below 10-point.

Messrs. Bruce Wiswell and Don Gilbert, Rite Aid, testified in opposition of a 12-point minimum font requirement and stated Rite Aid's support of a 10-point font requirement. They provided the board with sample vials wherein Rite Aid labels were printed in 12-point and then in 10-point font, affixed to sample vials, demonstrating that the 10-point font works best for them. They testified that they believe patients will not use a larger bottle that may be required to fit a label with 12-point font, and that patients will put their pills into a different container (i.e., decanting) which would not have the prescription label on it. Mr. Wiswell also testified that Rite Aid includes additional information on a prescription label for special services, things they define as patient-centric.

Ms. Angela Blanchard of Target Corporation testified that Target shares a commitment to ensure consumer-friendly labels. She stated that Target's label was developed based on research and consumer studies. She addressed font size on the label currently used at Target, indicating a variety of font sizes, from 9.5 for the guest name and up to size 14-font for the directions for use. She clarified that the patient's name is up to 10-point font; the maximum font utilized for the drug name is 14-point; and the maximum font size for directions is 13.5-point. She stated the 14-point font is the exception rather than the rule. Ms. Blanchard testified that 85% of dispensed drugs end up in a smaller bottle, and that should the instructions exceed five lines, the font is shrunk down accordingly. She stated that Target prioritizes instructions and the drug name. Ms. Blanchard testified as to her support of allowing some flexibility and that the board not be overly prescriptive on the font size.

Ms Margie Metzler representing Gray Panthers and the Older Women's League, and as a member of CARA, testified in support of a 12-point font requirement, citing the needs of seniors and difficulties experienced when trying to read smaller fonts.

Ms. Ria De Groot, a member of California Alliance for Retired Americans testified in support of a 12-point font requirement. She added that she needs to utilize reading aids for anything smaller than 12-point.

Ms. Nan Brasmer, California Alliance of Retired American, testified that on behalf of CARA's 850,000 members, she supports the use of a 12-point font.

Ms. Jan Howe, RN, testified that she is a member of CARA and the California Nurses Association. She testified that she concurred with the comments offered by Liz Abbott and Nan Brassmer, and that she is in support of the 12-point font requirement.

Ms. Missy Johnson of the California Retailers Association stated that they have severe issues with the 12-point font requirement and they would prefer for it to be a 10-point font for the patient's name, the drug name and the prescription number. She stated they are not recommending that 12-point font be a mandate at all.

The NACDS, CPhA and CRA ask that the board require 10-point typeface for the patient name, prescription number and drug name and that the pharmacy use discretion in how the other items are placed on the label. If a patient needs a larger font, Ms. Staples stated that along with the prescription container, their pharmacies are able to provide patients with a separate sheet of

paper in a larger font, if so requested. Ms. Lynn Rolston of the California Pharmacists Association testified that pharmacies generally do their best to make the font as large as possible, but that patients also complain about too large a vial size. She stated that the board should work more with a separate paper auxiliary label that is easy for patients to work with.

The NACDS, CPhA and CRA states concern about whether use of a standard font type is justified in light of the cost associated with that change.

Board Response

In response to comments received during the 45-day comment period and in response to testimony received at the regulation hearing, the board modified the text of § 1707.5.(a)(1) to specify that the items specified in subparagraphs (A) through (D) shall be printed in at least a 10-point sans serif typeface (versus 12-point). (Other modifications made for the 1st 15-day comment period are summarized in this document under the various subdivisions to which the modifications apply.)

Regarding the stated concern with cost associated with a change in standard font type, no current font type requirement exists. By establishing such a requirement, some pharmacies may have to change the font typeface and size they use for their prescription labels; others may not need to change that information. The NACDS, CPhA and CRA offered no information or data to indicate what costs may or may not be realized as a result of complying with the rulemaking.

In response to the specific modification made to §1707.5.(a)(1) during the first 15-day comment period the board received two letters in support of the modifications made. The board received five letters of objection to all modifications made to the original proposed text from the following persons: Senator Ellen Corbett, Syed Sayeed of Consumers Union, Anthony Wright of Health Access, Ken McEldowney of Consumer Action and David Swankin of Citizen Advocacy Center [joint letter], and Ms. Suzanne Winters. The board received 1,078 (like) letters objecting to the modification to 10-point font and urging the board to use 12-point (or “larger font size” for the most important information on the prescription label. The board received one recommendation to require that a reading lens be provided if 9- or 10-point font is specified.

Board Response

In response to comments received during the first 15-day comment period, the board again modified the text of § 1707.5. (a)(1) to specify that the items specified in subparagraphs (A) through (D) shall be printed in at least a 10-point sans serif typeface “or, if requested by the consumer, at least a 12-point typeface....” The board made this modification to provide consumers with the option of receiving at least 12-point font for the items specified in subparagraphs (A) through (D), if so requested. The board determined that a compromise to require a minimum 10-point sans serif font on all prescription container labels, with the requirement that if the patient requests, the pharmacy shall provide a prescription container label with a minimum 12-point sans serif typeface, is responsive to comments received and serves the needs of the patient.

In response to the 2nd 15-day modified text, the board received one letter of support from a pharmacist who stated he changed the layout of his prescription label to conform to the requirements of the regulation, as modified, and that he was pleasantly surprised that the outcome looked nice and did improve readability.

The board received one recommendation to remove from §1707.5.(a)(1) the words "... or, if requested by the consumer, at least a 12-point typeface...." The board received another recommendation to modify the language §1707.5.(a)(1) to read "...or, if requested by the consumer at the time the prescription is first presented, at least a 12-point typeface...."

One comment asserted that requiring a 12-point font on a prescription label may prevent the patient's full name from being printed on the label.

One independent pharmacist provided public comment and prepared for the board's observation sample prescription labels on 20 dram vials utilizing 12-point font and formatted to conform to the requirements of §1707.5.(a)(1). This pharmacist stated that the 12-point font requirement was reasonable, easy to accommodate, and that modifying their pharmacy's label to accommodate the proposed regulation required little effort and could be done with minimal impact to pharmacy operations. He stated that to comply with the requirements of the regulation, he may need to use larger vials. He further offered that he contacted his prescription bottle manufacturer regarding the cost of prescription bottles, and stated he may incur a minimal increase in the cost of his prescription bottles, citing \$0.02 - \$0.03 per bottle. This pharmacist indicated the 2 cent to 3 cent increase is not reflective of discounts that he perceived larger chain pharmacies might receive based on order sizes.

Board Response

The board recognizes that because no current requirements exists (with respect to the layout of a prescription label, or to the font size(s) or typeface utilized), pharmacies currently provide patients with prescription labels printed in a wide variety of fonts, font sizes, typefaces and bottle sizes. At many of the SB 472 public forums and during many of the Board Meetings, the board viewed a variety of actual prescription drug containers/labels which reflected a wide variety of font sizes, typefaces and formats – some using a font size as small as 6-point. By promulgating this regulation, the board recognizes that some pharmacies will need to change their prescription drug labels; others may need to use different prescription drug bottles to accommodate a standardized "patient-centered" label; and others may need to change both their label and bottle. The board believes that establishing conformity and consistency in the information presented on a prescription drug container medication label will benefit the patient and will help reduce medication errors.

Section 4076 of the Business and Professions Code specifies required elements of a prescription drug label. The board – through this rulemaking – is establishing a standardized, patient-centered prescription drug label for all prescription drugs dispensed to patients in California. This rulemaking is not changing what information is required to be on a prescription drug label – rather, the regulation specifies the format,

type size, and typeface of the prescription label, as well as other requirements. As reflected in the Initial Statement of Reasons, the board considered its mandate (Business and Professions Code § 4076.5), Model Guidelines of the National Association of Boards of Pharmacy, research, studies, testimony and comments from health literacy experts and proponents, consumers, consumer groups and industry.

Some data reflect that a minimum 12-point sans serif typeface is recommended or is more readable than a smaller font size. Other data reflect that 10-point font is easier to read than 8-point font. In crafting the regulation text, the board also considered its public protection mandate specified in section 4001.1 of the Business and Professions Code. The board also considered comments received during the rulemaking process and determined that the adopted text is responsive to those consumers who want at least a 12-point font for the “clustered” patient-centered items (specified in subdivision (a) of the regulation), and that the adopted text is responsive to the needs of pharmacies.

The board rejects the assertion that 12-point typeface is “not reasonable” and would result in greater costs. As previously stated, and with the exception of cost information provided by an independent pharmacy, the board received no data to represent what actual costs are or what estimated costs may be realized as a result of this rulemaking.

The board rejects the assertion that by using 12-point font for the “clustered” patient-centered items, as specified in §1707.5.(a)(1), that the patient’s full name may not fit on the prescription drug container label. Business and Professions Code section 4076 requires that the name of the patient be placed on the prescription drug container label. This rulemaking does not alter that requirement. The board does not specify in this rulemaking what size label is required to be used by a pharmacy, and no current requirement exists. As previously stated, the board recognizes that a pharmacy may have to use a label size that can accommodate the requirements of the regulation. The board believes that establishing conformity and consistency in the information presented on a prescription drug container medication label will benefit the patient and reduce medication errors.

To those that claim added cost and impact on the environment as a result of using a larger prescription drug bottle to accommodate a larger label, the board is not aware of any data to support claims that (for example) a 30 dram vial has a larger impact to the environment than a 20 dram vial, nor was any data offered to support claims of added cost and impact to the environment.

The board recognizes the efforts of the National Association of Boards of Pharmacies and the NABP Task Force to establish minimum national standards for prescription drug container labels; however, these recommended standards are not enforceable by any state or federal regulatory agency. The board believes that the regulation text adopted is reflective of underlying data, is responsive to the comments of those who wish to have a 12-point font on their prescription drug container label, and establishes how “patient-centered” items are formatted on a prescription drug container label – all of which will benefit the patient. The minimum standards adopted through this regulation will be

enforced by the California State Board of Pharmacy. Also, and while not required to do so, the board adopted text to specify that it will re-evaluate the requirements of the regulation by December 2013 to ensure optimal conformance with Business and Professions Code § 4076.5.

The board considered comments received during the public comment periods, as well as testimony and public comment received at the regulation hearing, and determined that a compromise to require a minimum 10-point sans serif font on all prescription container labels, with the requirement that if the patient requests, the pharmacy shall provide a prescription container label with a minimum 12-point sans serif typeface.

General Comments regarding font size and type

The board received many general comments about the use of 12-point typeface as a minimum, but none made specific recommendations to modify the regulation text, nor did they state explicit objections to the modified text. These general comments are summarized below but are not responded to as they do not address any specific modified text, state objection to the specific modified text or comment on the procedures followed by the board.

Senator Corbett stated in a letter following the 2nd 15-day comment period that in the board's latest proposal, the board recognized it is feasible to use 12-point font on labels, but leaves it up to those most vulnerable to request larger font. She adds that if the board were truly interested in protecting vulnerable consumers, 12 point type should be the standard.

Dr. Colenbrander states that adequate legibility of pharmacy labels is important to avoid medication errors and states that no matter what print size is used, there will be some people for which it is not large enough. He adds that there is a practical limit large the print can be on a given label. He further states that with an appropriate magnifier, reading pharmacy labels is still possible for 98% of users whose vision is too poor to read a standard label. Dr. Colenbrander provided an example of the Target pharmacy label and provided background on how it was developed. He provided data on the various font sizes and text characteristics utilized on the label. He added that the use of smaller print for some items frees up space for larger print for more important items.

Ms. Mary Staples representing NACDS stated that their pharmacies are willing and able to provide patients with a separate sheet of paper showing a large font size, upon the patient's request. She stated their stores currently provide this service which is appreciated by their patients.

Consumers Union stated in a letter following the 2nd 15-day comment period that the regulation "falls short of creating a truly patient-centered, standardized prescription label for California." The letter further states that 12-point font minimum for most important parts of a label would make medications safer to take for all Californians. He adds that consumers should receive readable labels without having to ask for them.

Other comments include

- General comments regarding font size and the safety of consumers
- Comment urging the board to restore the 12-point minimum font, or to consider the board's 'stance' on 12-point
- 12-point should be the standard and is vital for quality care; it is the minimum size for readability
- Anything less than 12-point font on a medicine label is a disservice to the elderly
- The board should commit to one font size, not use both 10- and 12-point
- The difference between 10- and 12-point font is not that great
- As the font increases, less information will fit on a current, standard label size
- Bigger labels will require larger containers
- 10-point font is too small
- Comments that larger vials will be needed to accommodate a label that conforms to the regulation; and that larger vial sizes will result in increased costs and storage issues for patients
- Comment asking the board to keep in mind that financial resources are limited for small, independent pharmacies
- There is huge room for error if patients must request a larger font
- The modifications fall short of creating a truly patient-centered standardized label
- 12-point would make medications safer to take
- Patients shouldn't have to ask for larger font
- It is critical that consumers have clear and readable size printed directions

§1707.5(a)(1)(B)

The California Medical Association stated their support of the generic name of the drug on prescription labels as identified in §1707.5(a)(1)(B). They believe this requirement will facilitate patient's understanding of their prescribed medication as well as increase compliance with the directions for use.

Board Response

The board appreciates the comment of the California Medical Association and agrees that including the name of the drug as one of the "clustered" patient-centered items on the prescription label will facilitate a patient's understanding of their prescription medications, as well as facilitate increased compliance with the directions for use.

§1707.5(a)(1)(D) – Including Purpose or Condition on the Label

In response to the initial proposed text, Ms. Veronica Ramirez of the California Medical Association stated that §1707.5(a)(1)(D) does not meet clarity and consistency standards outlined by the Administrative Procedures Act. Specifically, §1707.5(a)(1)(D) states that the purpose or condition of the drug must be listed on the prescription label if "its inclusion on the label is *desired* by the patient." CMA commented that it is impossible for a pharmacy or prescriber to know whether the inclusion of the purpose or condition is "desired" by the patient if this patient never requests such inclusion. CMA stated that the language would subject

individuals and entities to potential liability should it be found that such a desire existed, even if it was not explicitly requested.

Board Response

Following the 45-day comment period and the regulation hearing, and in response to the California Medical Association's comment, the board modified the text of section 1707.5.(a)(1)(D) to strike the word "desired" and insert "requested," resulting in the first 15-day comment period.

During the first 15-day comment period, the board received comments in support of placing the purpose or condition on the prescription label. One comment asserted that a patient should not be required to request that the purpose be on the label. The CMA recommended that to improve clarity, the purpose or condition should be included on the prescription label if it is specified by the prescriber.

During the 1st 15-day comment period, the board received five letters of objection to all modifications made to the original proposed text from the following persons: Senator Ellen Corbett, Syed Sayeed of Consumers Union, Anthony Wright of Health Access, Ken McElowney of Consumer Action and David Swankin of Citizen Advocacy Center [joint letter], and Ms. Suzanne Winters.

Board Response

In response to comments received during the first 15-day comment period, the board modified the text of §1707.5.(a)(1)(D) to strike the last half of the sentence – the provision that specifies that the purpose or condition be on the label if it is requested by the patient, resulting in a second 15-day comment period. The board believes that this modification ensures the language of the regulation is consistent with the statutory provision that authorizes the purpose or condition to be placed on the prescription label, Business and Professions Code section 4076(a)(10). The board believes this modification is responsive to the comment to provide clarity, and is also consistent with the statutory language that authorizes the purpose or condition to be placed on the label.

In response to the second 15-day comment period, the board received one recommendation from Independent pharmacist Stephen Rosati, RPh, who recommended that the board modify the language of §1707.5.(a)(1)(D) to specify "purpose or condition, if entered on to the prescription by the prescriber or requested by the patient or patient's representative" – adding that this language would prevent confusion for a patient who self medicates or if medication is given by another individual. In addition, the board received general comments in support of the purpose or condition being placed on the label, adding that few patients know they can request such services and that the information is necessary for those who take multiple medications. One general comment indicated that adding the purpose of the medication to the prescription label should be at the discretion of the physician and pharmacist. Another general comment asserted that compliance with 1707.5.(a)(1)(D) may require a careful assessment of language skills.

Board Response

The board considered the comments received during the second 15-day comment period at the June 10, 2010, Board Meeting. The board did not further modify the language of 1707.5.(a)(1)(D) to accommodate the recommendation received. The board believes the regulation text, as adopted, is consistent with the statutory provision that authorizes the purpose or condition to be placed on the prescription label, Business and Professions Code section 4076(a)(10).

§1707.5(a)(2) and (a)(3) – Emphasis and placement of other required items

During the 45-day comment period, the NACDS, CPhA and CRA requested that the board allow pharmacists the flexibility to use “different means to highlight information.”

Board Response

It is not clear to the board, nor does the comment recommend, what “different means” the board should consider for inclusion in §1707.5.(a)(2) for added emphasis. The board did modify the language of §1707.5.(a)(2) to prescribe that the label shall (not ‘may’) use highlighting or blank space to set off the items specified in §1707.5.(a)(1) provides important patient safeguards, resulting in the first 15-day comment period.

During the 1st 15-day comment period, the board received five letters of objection to all modifications made to the original proposed text from the following persons: Senator Ellen Corbett, Syed Sayeed of Consumers Union, Anthony Wright of Health Access, Ken McEldowney of Consumer Action and David Swankin of Citizen Advocacy Center [joint letter], and Ms. Suzanne Winters.

In various discussions before the board, board members discussed a “check book” approach to clustering information on a prescription drug container label. This means that irrespective of what pharmacy a consumer / patient frequents to fill a prescription, the “patient-centered” items will always appear in the same format. For example, the consumer will know that the patient’s name will be the first item in those “clustered” items on a prescription label. The board believes that establishing conformity and consistency in how information is presented on a prescription drug container label will benefit the patient.

The board did not further modify the language of 1707.5.(a)(2) and believes the regulation text, as adopted, is consistent with the statutory provision that authorizes the purpose or condition to be placed on the prescription label, Business and Professions Code section 4076(a)(10).

§1707.5(a)(4) – Standard Directions for Use

Dr. Michael Wolf, North Western University, testified that the directions for use specified in the proposed regulation represent approximately 90% of all prescriptions. He stated this percentage is built on evidence and is supported by a review of approximately 350,000

medications. The information was also backed up by data in talking with Kaiser as well as in a much, much larger data set. He testified that it is important to dissect and order the different elements in an instruction, and he offered to provide the board instructions based on their actual use assessment.

The California Medical Association comments that proposed 1707.5(a)(4) is unclear. “The proposed phrases for use in describing when a prescription medication should be consumed are too broad.” CMA states that rather than using a phrase such as “take 1 tablet in the morning, one tablet at noon, and one tablet in the evening (§1707.5(a)(4)(J)) – the directions for use should instead indicate the appropriate time increments between doses. CMA asserts that if suggested time increments between doses are included in the directions for use, patient safety would be protected.

The NACDS, CPhA and CRA request that the board not mandate the specific directions as they are unnecessarily lengthy and repetitive and do not allow a pharmacist to use his or her professional judgment if such directions are needed.

In answer to a board member’s question, Ms. Staples testified that the directions for use not be specified at all and that technology and innovation not be limited or specified.

Ms. Lynn Rolston, California Pharmacists Association, testified that there may be concern over the term “pill” as initially proposed. She stated pharmacists like to be more specific, i.e., “tablet” or “capsule”, etc.

Dr. Michael Wolf, North Western University, recommended that the term “pill” be used in lieu of the word “tablet.”

Mr. Rosati testified that the “form” of the drug should be in 12-point font. He said he thinks it is important for the consumer to realize whether they have a capsule or tablet and that, if it is not required, it could possibly disappear from the label. Mr. Rosati provided an additional seven phrases and recommended they be included in proposed 1707.5(a)(4).

Board Response

Underlying data utilized by the board reflect that the standardized “directions for use” specified in §1707.5(a)(4) may apply to approximately ninety percent of all prescription dosing instructions (as specified by a prescriber on a prescription document). The board believes that the directions for use specified in 1707.5(a)(4) are clear. Existing law requires the directions for use of the drug be placed on a prescription label (see §4076(a)(2) of the Business and Professions Code). The adopted regulation specifies in §1707.5(a)(4) that “when applicable” the directions for use shall be used. A prescriber’s order may contain a direction for use that is not provided in proposed 1707.5(a)(4). In that case, the pharmacist would place on the label the directions for use that is specified by the prescriber. It is within the scope of a pharmacist’s practice to determine if additional information (such as time increments between doses) should be placed on the prescription label, if he or she determines it is necessary for the safety of the patient.

To facilitate the translation of the directions for use into at least five languages other than English and in order to have those translations published on the board's Web site by October 2011 (as specified in §1707.5.(b)), the board did not vote to expand the directions for use to include additional phrases. However, pursuant to subdivision (e) of the regulation, the board will re-evaluate the requirements of the regulation by December 2013. The board will, at that time, determine if the directions for use or other provisions of the regulation should be modified.

If one of the standard phrases (specified in §1707.5.(a)(4)) are not appropriate for the prescription, the board expects the pharmacist to use his or her professional judgment as to placing the appropriate dosage form on the prescription drug label. Current regulations (16CCR §1707.1.) require that the dosage form for each prescription dispensed by the pharmacy be maintained in the patient medication record. Likewise, 16CCR §1707.2.(c) requires a pharmacist to include in an oral consultation the dosage form of the drug dispensed.

With respect to placing the "appropriate dosage form" on the prescription medication container label, the board modified the regulation text after the 45-day comment period to add subdivision (f), defining "appropriate dosage form" and to amend the standard directions for use specified in §1707.5.(a)(4) to strike the word "tablets" and specify that the pharmacist shall insert the appropriate dosage form. Subdivision (f) does not require that only those dosage forms indicated be used in the standard directions for use as specified in §1707.5.(a)(4). Rather, the board expects that a pharmacist will use his or her professional judgment to determine if and what appropriate dosage form is included in the standard directions for use, if appropriate to the prescription order.

During the 1st 15-day comment period, the board received five letters of objection to all modifications made to the original proposed text from the following persons: Senator Ellen Corbett, Syed Sayeed of Consumers Union, Anthony Wright of Health Access, Ken McEldowney of Consumer Action and David Swankin of Citizen Advocacy Center [joint letter], and Ms. Suzanne Winters.

The board did consider comments received during the 1st 15-day comment period but did not further modify the language of the standard directions for use phrases specified in §1707.5.(a)(4).

§1707.5(b) – Board to Publish Printed Translations of Directions for Use

The California Medical Association suggests that proposed 1707.5(b) be expanded to require the Board to publish translations of these directions on its Web site into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California.

While the proposed regulation requires translation into at least five languages, Deeana L. Jang, JD, APIAHF, urges the board to raise the minimum number to at least 15 languages by October 2011, and at least five additional languages in each of the following years.

Mr. Marty Martinez of CPEHN, Ms. Goodfriend-Koven, Ms. Darlene March, and Luis Miguel PhD recommend that the board place on its Web site standard labels translated into at least the 14 languages spoken by groups of 10,000 or more limited English speakers in California. Mr. Martinez, Dr. Miguel and Ms. March assert the cost for these translations is minimal with a large health payoff. Mr. Martinez provided census data indicating which languages are the top limited English Language.

Ms. Elizabeth Abbott of Health Access California recommends that the board provide pharmacies with standard label language in at least the 14 threshold languages delineated for language assistance in California based on population size.

Ms. Doreena Wong of the National Health Law Program (NHeLP) testified that the number of languages specified in the proposed regulations does not properly cover enough of the population, given the large population of limited English proficient patients in California.

Ms. Doreena Wong, NHeLP, and Ms. Linda Okahars, Asian Health Services, testified that the number of languages in which the standardized directions for use are available should follow the Medi-Cal managed care threshold requirements.

Ms. Doreena Wong stated her support of the provision requiring an oral language translation of the directions for use, but recommended the board publish the translation of the standard directions for use sooner than October 2011.

NHeLP recommends that for patients who cannot read or understand English but can read in another language, the pharmacy shall provide a prescription container labeled with the components specified in subdivision (a) in the language of the patient.

Board Response

In support of the board's efforts to establish standardized directions for use, the California Endowment has made a commitment to fund a project with Dr. Michael S. Wolf to translate and field-test the directions for use into the five predominant non-English languages in California. The field study conducted for this purpose will fully vet the translation of the standard directions for use specified in §1707.5.(a)(4). The board believes that utilizing the resources of the California Endowment, as well as a nationally recognized expert in health literacy to vet translations for this purpose, is prudent and that such a study could easily expand to other languages in the future. Dr. Wolf testified that the regulation does not limit the translations to five languages, rather, the text says at least five. He clarified that the California Endowment has pledged to fund the development and vetting of the directions for use (specified in §1707.5.(a)(4), and that the translations will be provided to the board by October 2011 (as specified in §1707.5(b)). Dr. Wolf added that the effort is a very intensive process and, while he would like to include more languages, based on the timeline provided in the regulation, translation of the standard directions for use in five languages is reasonable. Therefore, the board rejects the recommendation to publish the specified directions for use in five languages other than English to its Web site prior to October 2011.

As specified in the regulation, and to facilitate the use by pharmacies and pharmacists, the board will publish on its Web site translations of the standard directions for use (as specified in §1707.5.(b)) into five languages other than English. The board considered comments to expand the minimum number of languages specified in §1707.5.(b), however, in consideration of directive provided in section 4076.5 of the Business and Professions Code to require, on or before January 2011, a standardized, patient-centered prescription drug label on all prescription medicine dispensed to patients in California, the board determined that – at this time – it will not require that a pharmacy or pharmacist provide patients with written translated prescription drug labels

The adopted regulation does not prohibit a pharmacy from providing translated prescription drug labels to patients. The board did consider the needs of limited-English proficient patients and determined that – at this time – providing fully vetted translations into five languages other than English of the standard directions for use, as well as the oral language interpretive services required by §1707.5.(d) of the adopted regulation do serve the needs of LEP patients.

The board is committed to the establishment of a standardized, patient-centered prescription label for all Californians. To that end, and to further consider and address the needs of limited-English proficient patients (and as specified in subdivision (e) of the regulation), the board will re-evaluate the requirements of the regulation by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

General Comments

The board also received general comments regarding printed translations of prescription drug labels and for the directions for use specified in §1707.5.(a)(4). These general comments are summarized below but are not responded to as they are outside the scope of the regulation, do not address any specific modified text, do not state objection to specific text, or do not comment on the procedures followed by the board.

The NACDS, CPhA and CRA state that for written translation services pharmacies are limited by the technology available. They state that French and Spanish are the only languages available for drug information translation today, and that the ability to translate consumer medicine information and MedGuides into other languages is limited. They state that such services are generally not available, printers lack the capability, and written translations are not available on demand.

The California Medical Association (CMA) supports the requirement that the board publish on its Web site a translation of standard directions for use into at least five languages other than English.

With respect to written translations, Mr. Rosati asserts that if a prescription label is translated, a pharmacist's screen should show the English directions on the same screen next to the

translated label, so that there can be some hope of ensuring that the correct directions are being provided to the patient.

Messrs. Bruce Wiswell and Don Gilbert of Rite Aid testified that they currently print translated languages on a separate sheet, along with an English translation so the pharmacist has a reasonable opportunity to do a legitimate quality assurance comparing the English to the other language. Mr. Wiswell testified that Rite Aid currently provides translations in 13 languages.

Ms. Nisha Agarwal, Director, Health Justice Program, New York Lawyers for the Public Interest, Inc. (NYLPI) stated that NYLPI is pleased that the proposed regulations require the board to publish on its Web site translations of the standardized directions for use into at least five languages.

Dr. Michael Wolf, North Western University, testified that they are the principle investigator leading the California Endowment Study to translate the directions for use into five languages other than English. He testified that the proposed regulation does not limit the translations to five, rather it is saying at least five. He clarified that there is funding for five languages. With the support of the California Endowment, Dr. Wolf testified that the language translations will be provided to the board within the time specified in the proposed text. He provided additional testimony on the approach that would be utilized to develop the translations. He stated this effort is a very intensive process and, while they would love to do more languages, he supports the regulation to provide five to begin with.

Ms. Nan Brasmer, California Alliance of Retired American, testified that CARA supports keeping translations very broad so that as many people as possible can be protected by having proper instructions both orally and in writing.

APIAHF states the board can do better than translation of directions in five languages. APIAHF states that the cost for translating 17 simple directions is minimal and is a one-time cost. APIAHF states that translation costs range from .20-.80 per word. APIAHF states that Healthy Families translates its application into 10 languages; the California Department of Social Services has a bilingual unit that translates social services notices into over 16 languages; and the California Department of Health Care Services has translated a Language Services Notice in 12 languages.

Deeana L. Jang, JD, APIAHF, asserts that the board can save on translation costs by providing a glossary of the terms already translated, citing services available in the State of Washington.

Ms. Tina Diep of Asian Health Services and Ms. Angela Chen (via translator) spoke in support of standard translation of common medication instructions. Ms. Chen stated she supports the regulation that pharmacies have instructions on the label translated into the patient's native language.

Mr. Marty Martinez, CPEHN, testified that prescription drug labels translated into the patient's language are vital for quality care and provided a list of what must be included in the board's final adopted regulations. In a letter dated January 4, 2010, Mr. Marty Martinez of the California Pan-Ethnic Health Network (CPEHN) stated that additional work needs to be done to create

stronger regulations for language access. He states that “the Board backed away from requiring labels to be translated into every patient’s primary language” and he further asserted that “this provision was in the recommendations submitted by staff to the Board.” He stated the provision (to require translated labels in every patient’s primary language) should be brought back.”

Ms. Elizabeth Abbott urged the board to include a requirement that a translation be placed on the label.

Ms. Ria De Groot, CARA, testified that written translations need to be provided, not just oral language translations. She stated that memory is a problem for seniors and that seniors need a written translation to reference should they need to reference the information after an oral language translation. She suggested that a patient could be provided with written instructions in English, and that the other side be provided in the translated language.

Ms. Doreena Wong stated the regulation does not *require* pharmacists to translate the items specified in proposed 1707.5(a)(1). She stated that without some kind of requirement for translation, it will be voluntary and may never be fully implemented. She referenced a New York settlement wherein seven of the largest chain pharmacies are required to translate drug container labels into six languages, adding that CVS, Rite Aid, WalMart, Target and Costco will be doing so nation wide. Ms. Wong recommends that the entire label be required to be translated, and that a phase-in period be utilized for implementation. She also recommended that when instructions for use specified by the prescriber do not conform to the items listed in subdivision (a)(4), the pharmacy shall secure its own translation.

Ms. Nisha Agarwal, Director, Health Justice Program, New York Lawyers for the Public Interest, Inc. (NYLPI) stated NYLPI’s support of provisions that pharmacies be required to provide translated prescription labels. She encouraged the board to incorporate stronger, mandatory language into its regulations regarding label translations. NYLPI is concerned that there is no requirement in the regulations for pharmacies to make these translated labels available to their customers. NYLPI provided background on a study conducted in New York which indicated that pharmacies overwhelmingly failed to provide their LEP customers with translated medication labels *despite having the capacity to do so*. In New York, that is now changing in response to a civil rights complaint NYLPI filed on behalf of community partners – which resulted in settlement agreements with all of the major chain pharmacies operating in NY. Under the settlements, CVS, Rite Aid, Costco, Target, Wal-Mart, A&P and Duane Reade pharmacies are required to make translated labels available in six languages and must add five more languages within six months of updating their computer systems to track language preference.

Ms. Nora Goodfriend-Koven, Ms. Darlene March, and Dr. Luis Miguel state that the board should provide pharmacies with standard labels translated into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California. They state that for non-standard labels and other languages, individual pharmacies could be responsible for providing translated labels. Ms. Goodfriend-Koven asserts that prescription drug labels translated into the patient’s language are vital for quality care.

APIAHF urges the board to add a provision in the regulation to require that pharmacies translate non-standardized labels in the most prevalent languages spoken in the service area.

Mr. Brian Kratt, Chief Executive Officer of RxTran provided information regarding resources available to pharmacies to provide on-demand translated Directions for Use (SIGs), stating that for small independent pharmacies, prices can be as low as \$50 per months for the equivalent translation of hundreds of thousands of SIGs per month into any 11 languages.

§1707.5(c) – Board to collect and publish on its Web site examples of labels

The board did not receive any comments specific to subdivision (c).

§1707.5(d) – Oral Language Interpretive Services

Mr. Marty Martinez of California Pan-Ethnic Health Network testified that in a pharmacy's policies and procedures, the board could require how to identify the patient's language, how interpretive services will be provided, and how the sample labels provided by the board will be utilized where appropriate.

Ms. Lynn Rolston of the California Pharmacists Association, testified and requested that the language in §1707.5.(a)(4)(D) state "in the patient's language, if available" [The board understands this comment to address proposed 1707.5(d).] She states that there are some dialects that translations services may not cover and, as proposed, it will be very difficult for pharmacies to find services to accommodate these languages. She requests modification to specify that such interpretive services be provided in a patient's language if that language is available for such interpretation. Ms. Rolston also requested that if the board requires pharmacies to have policies and procedures in place, that the board specifies what is to be included.

Lin Hokana, RPh, recommends that the following text be added to the last sentence of 1707.5.(d). He comments on the use of computer software to generate a label in a language other than English, asserting such use is illegal.

"The pharmacist is encouraged to also furnish written directions for use in the patient's native language that match the directions on the label."

Ms. Linda Okahars, Asian Health Services, testified that the patient's language be identified in the patient record.

During the 1st 15-day comment period, the board received five letters of objection to all modifications made to the original proposed text from the following persons: Senator Ellen Corbett, Syed Sayeed of Consumers Union, Anthony Wright of Health Access, Ken McEldowney of Consumer Action and David Swankin of Citizen Advocacy Center [joint letter], and Ms. Suzanne Winters.

Board Response

In consideration of comments received during the 45-day and subsequent comment periods, as well as testimony received at the regulation hearing held January 20, 2010, the board modified subdivision (d) of the regulation to specify that a pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label, as specified in §1707.5.(a), in the patient's language. Subdivision (d) specifies minimum requirements for the pharmacy's policies and procedures and requires the pharmacy – at minimum – to provide interpretive services in the patient's language, if interpretive services in such language are available, as specified.

The board believes the adopted text represents a reasonable balance between the needs of LEP patients and the requirements placed on pharmacies to provide such services. The board further believes that the requirements specified in §1707.5.(d) are responsive to the comments received and are reasonable given the directive in Business and Professions Code section 4076.5 to require a patient-centered prescription container label by January 2011.

However, the board is committed to the establishment of a standardized, patient-centered prescription label for all Californians. To that end, and as specified in subdivision (e) of the proposed regulation, the board will re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Letters of objection to the modifications made to subdivision (d) were received during the 1st 15-day comment period.

Ms. Doreena Wong states that the regulations should require that the primary oral and written language of the patient be recorded in the pharmacy's patient medication profile. She states that with this requirement, the pharmacist will know what kind of services the patient may need.

Ms. Linda Okahars, Asian Health Services, also testified that the patient's language should be identified in the patient's record.

Board Response

The board believes that it is reasonable that a patient's preferred language be identified. In light of the comments received, the board modified proposed 1707.5 to add subdivision (f) to require that a pharmacy have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) and that the policies and procedures, at a minimum, include the selected means to identify the patient's language and to provide interpretive services in the patient's language.

General Comments

The board received general comments regarding oral language interpretive services to patients. These general comments are summarized below but are not responded to as they are either outside the scope of the regulation, do not address any specific text, do not state objection to specific text, or do not comment on the procedures followed by the board.

Ms. Nisha Agarwal, Director, Health Justice Program, New York Lawyers for the Public Interest, Inc. (NYLPI) provided background that NYLPI is a nonprofit civil rights law firm, and is a national leader in the effort to promote language access in pharmacies for people with limited English proficiency. NYLPI offers comments to strengthen the proposed regulations, based on experiences in New York.

NYLPI states that implementing SB 472 with strong regulations will send a forceful message to consumers and providers across the country that the civil rights of LEP individuals are to be protected and honored. NYLPI states that California is viewed as a leader in advancing the rights of LEP consumers, and that other states are looking to California to learn from the board's efforts to standardize and translate prescription drug labels.

Ms. Jan Howe, RN, a member of CARA and the California Nurses Association stated that as a practicing nurse, Kaiser made available oral interpretive services via phone. As an advice nurse and as a home care nurse for hospice, Ms. Howe testified that she could reach a translator anytime she needed to. She supports the board's regulation to change prescription labeling to increase safety for California patients.

Ms. Linda Okahars of Asian Health Services testified as to some of the challenges the Asian Health Services experience in terms of trying to overcome language barriers for their patients. She stated that Asian Health Services serves approximately 20,000 patients and that approximately 90 percent are limited English speakers.

Ms. Doreena Wong, National Health Law Program, stated that the proposed regulations do not meet the intent or the statutory requirements or the needs of patients with limited-English proficiency (LEP). Ms. Wong asserts that there are seven specific "requirements" (inference to section 4076.5 of the Business and Professions Code).

Ms. Bush of the California Grocers Association comments that while some pharmacies already provide an oral language translation of the prescription contents if requested by the patient, not all pharmacies are able to provide this service without economic impact. Ms. Bush states that the regulation presents legal concerns for pharmacies that would be held liable if medication information was misinterpreted in translation; and that this service does not come without an economic impact; no specific data or information regarding economic impact was offered to the board.

Mr. Don Gilbert of Rite Aid testified that Rite Aid currently provides oral language translations via phone in approximately 150 languages.

Mr. Marty Martinez of California Pan-Ethnic Health Network testified that all patients who do not speak English must have the right to have their prescription drug instructions orally interpreted, as required in the regulation. Mr. Martinez testified that final regulations adopted by the board must provide for both a written translated label and an oral interpretation of the instructions for each patient who needs it. Mr. Martinez expressed concern that the regulation is sufficient to improve the care and safety of the 40% of Californians who speak a language other than English at home.

NHeLP does not believe that the initial text reflects the statutory requirement that the board take into consideration the needs of LEP patients. Ms. Wong adds that there are other federal and state requirements and guidelines to ensure linguistic access to LEP patients by pharmacists in various contexts, and provides references to various federal and state statutes, regulations and guidelines.

Ms. Deanna Jang of the Asian Pacific Islander American Health Forum (APIAHF) states that ensuring that effective communication takes place between patients and pharmacists is critical to patient adherence to medication instructions and prevention of adverse events as a result of failure to adequately communicate or consult the patient.

Ms. Goodfriend-Koven suggested that the board provide pharmacies with a listing of certified translators (by the American Translator's Association) and qualified interpreters (such as graduates of programs at the community colleges), so that those who do not speak English well can have their prescription drug instructions orally interpreted. She adds that pharmaceutical counseling is vital, and either telephonic or face-to-face interpreting needs to be part of the services offered to patients who cannot yet speak English.

General Comments regarding a Notice to Consumers

Throughout the rulemaking process, the board received comments related to oral interpretive services or printed/written translations of prescription labels or specified elements of a prescription label. Many of these individuals indicated in writing or testified as to a patient's right to be notified that services are available to them. The board believes that providing a notice to consumers advising them of the availability of oral language interpretive services may be reasonable. The board discussed modifying the regulation to include such a notice but determined that modifying the current rulemaking would sufficiently expand the scope of the rulemaking and may unduly delay action to implement a standardized, patient-centered prescription label beyond January 2011. Therefore, the board determined that it would not expand the scope of the rulemaking for this purpose, but directed staff to draft possible regulatory text for a separate rulemaking on the matter. The board first considered possible text for such a notice at its June 2010 Board Meeting.

A summary of comments received regarding a requirement to notify a patient of oral interpretive or translation services is below but are not responded to, as the board determined this was outside of the scope of the rulemaking.

Ms. Elizabeth Abbott of Health Access California testified that all patients with limited English proficiency should have the right to have their prescription drug instructions orally interpreted by a health professional working within his or her field of clinical expertise. She testified that patients are entitled to these services and that a notice of such services should be required.

Dr. Michael Wolf, North Western University, testified in support of a notice to consumers advising them of their right to request oral translations.

Ms. Doreena Wong recommended that the patient not be required to request oral interpretive services, but that the patient be notified of the right to such services.

Deeana L. Jang, JD, APIAHF, states that the proposed regulations only require an oral language translation of the prescription container upon request of the patient. APIAHF asserts that unless the patient is aware that this request can be made, the patient is unlikely to request it. APIAHF urges the board to require that pharmacies post notices informing limited English proficient persons of their rights under the board's regulations and under Title VI. APIAHF states that pharmacies must be required to provide a notice to patients that interpreter services are available at no cost to persons with limited English proficiency.

Ms. Doreena Wong testified that the regulation does not require that a notice be provided to patients informing them of their right to have an oral language translation, if they so request. Ms. Wong States the board should have a standard notice that is posted in the pharmacy, similar to that of the Notice to Consumers, so that LEP patients know their rights.

§1707.5(e) – Board to re-evaluate the requirements of the regulation by December 2013

The board did not receive any comments specific to subdivision (e).

§1707.5(f) – Definition of “appropriate dosage form”

Ms. Lynn Rolston, California Pharmacists Association, testified that there may be concern over the term “pill” as initially proposed. She stated pharmacists like to be more specific, i.e., “tablet” or “capsule”, etc.

Dr. Michael Wolf, North Western University, recommended that the term “pill” be used in lieu of the word “tablet” be used.

Board Response

With respect to placing the “appropriate dosage form” on the prescription medication container label, the board modified the regulation text after the 45-day comment period to add subdivision (f), defining “appropriate dosage form.” Subdivision (f) does not require that only those dosage forms indicated be used in the standard directions for use as specified in §1707.5(a)(4). Rather, the board expects that a pharmacist will use his or her professional judgment to determine if and what appropriate dosage form is included on the prescription label. The board believes that modifying the regulation to add subdivision (f) to define appropriate dosage form is responsive to comments received.

During the 1st 15-day comment period, the board received five letters of objection to all modifications made to the original proposed text from the following persons: Senator Ellen Corbett, Syed Sayeed of Consumers Union, Anthony Wright of Health Access, Ken McEldowney of Consumer Action and David Swankin of Citizen Advocacy Center [joint letter], and Ms. Suzanne Winters.

The board considered comments received during the 1st 15-day comment period and did not further modify the language of §1707.5.(f). The board believes the adopted text which defines an “appropriate dosage form” to use within a standard directions for use, if applicable, is clear and provides specificity.

Comments regarding Clarity and Consistency of the regulation

Ms. Veronica Ramirez of the California Medical Association stated support of the intent of the proposed regulations to improve health care literacy and to reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. However, CMA has concerns over the clarity and consistency of the current proposal, specifically §1707.5(a)(1)(D), and CMA urges the board to amend the proposed regulations. CMA did not specify what components of the regulation text lacked clarity or consistency.

Board response

The board does not agree that the regulatory text lacks clarity or consistency. No recommendations or objections were indicated specifying what components of the regulation lack clarity or consistency.

GENERAL COMMENTS

During the rulemaking process, the board received general comments regarding a variety of topics. The comments below are aggregated and summarized by topic, but are not responded to as they are either outside the scope of the regulation, do not address or make recommendations to any specific text, do not state objection to specific text, or do not comment on the procedures followed by the board.

General comments in support of the rulemaking

Mr. Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy spoke in support of the board's efforts to adopt or modify proposed 16 CCR §1707.5.

Mr. Catizone stated that NABP's support is founded in the findings of the NABP Task Force on Uniform Prescription Labeling Requirements. He stated that the results of the Task Force have only minor differences to the board's proposed regulation and agrees that the patient label is a critical piece of information – for which there are no alternatives to helping a patient understand and comply with their medication regimens. Mr. Catizone stated that the board's proposed regulation addresses the three critical issues as mandated by SB 472: that current wavering requirements in place in California and across the country do not address critical elements of the prescription label, such as what is necessary, what the font size should be, and what is understandable for the patient.

Mr. Catizone stated that he had reviewed the comments submitted during the 45-day comment period by those groups who oppose the board's efforts, and that he does not agree with those comments.

Mr. Catizone stated that the NABP's Task Force analysis confirmed the findings of the Board of Pharmacy that certain information needs to be mandated; certain information on the label needs to be at a different font size; and certain information needs to appear on the label but does not need to be highlighted.

Mr. Catizone stated that he does not agree with the contention that the proposed regulation would be overly burdensome for pharmacies to implement. In support of this, Mr. Catizone stated that research conducted by NABP and participants in the NABP Task Force helped design the label based on current systems that are in place in pharmacies, some of which operate in various states throughout the country – the same label components that are proposed by the Board of Pharmacy.

Mr. Philip Swanger, California System of Health-System Pharmacists, spoke in support of the proposed regulation. He states that CSHP represents approximately 4,000 pharmacists, pharmacy technicians, and associates that practice in varied settings, including hospitals, ambulatory care, and long-term care. He stated that the proposed regulation was shared with CSHP's board and that they have received no opposition to the proposed rulemaking from their board. Mr. Swanger further testified that CSHP was a strong supporter of SB 472.

Dr. Steve Gray, Kaiser Permanente, spoke in strong support of a regulation that requires standardized, readable prescription patient-centered prescription label. He also testified in

support of translations in at least five languages; in modifying the language “pill” to that of an appropriate dosage form, and alternative language for interpreter services especially if that requires pharmacies to establish policies and procedures.

Mr. David Grant, Director of Health Policy and Executive Director of Senior Action Network spoke in support of the proposed regulations. He testified he is speaking on behalf of consumers who originally helped pass the enacting legislation. He added that there are approximately 4.5 million seniors, taking an average of 8.5 prescriptions each. He testified that medication errors is one of the leading causes of readmission to acute care hospitals. He urged the board to adopt the regulations as proposed.

Ms. Diana Madishi, a member of CARA and of a small senior group in Placer, spoke in support of the proposed language. She testified to her support of a label, even if larger bottles are required. She also testified as to her support of the directions for use as it relates to the administration of pain medications.

General comments not in support of the regulation

Ms. Kara Bush of the California Grocers Association provided background on the CGA, as well as membership data. Ms. Bush states that many of its member grocery companies operate full service pharmacies. Ms. Bush states that the proposed regulations do not meet intended objectives. She adds that for CGA members to comply with the proposed regulations, the requirements must be cost effective, feasible and practical for pharmacy retailers.

General comments regarding requests for exemption from rulemaking

The board received general comments requesting exemption from the requirements of the rulemaking. Board counsel indicated that Section 4076.5 of the Business and Professions Code requires that the prescription drug label requirements apply to “all prescription medicine dispensed to patients in California.” Therefore, there is no statutory authority for the board to authorize exemptions or “opt-out” waivers of those labeling requirements.

Comments related to requests for exemption from the rulemaking are summarized below but are not individually responded to, as they are outside the scope of the current rulemaking.

Ms. Paige Tally, Director of the California Pharmacists Association’s Long-Term Care Management Counsel recommended an amendment to exempt from the requirements of regulation prescription drug medications dispensed to patients in facilities licensed pursuant to section 1250 of the Health and Safety Code. Mr. Greg Light and Mr. Lee Myer, also representing CPhA’s Long-Term Care Management Counsel, testified in support of the letter submitted by CPhA during the 45-day comment period noting the requested exemption. Mr. Light testified as to the various dispensing methods utilized at skilled nursing and other facilities, emphasizing that the prescriptions dispensed for these patients are never in control of the resident, nor are they self-administered. He stated that, in these settings, the prescription drug medications are controlled and administered by nurses. He asserts that these facilities adhere to regulations and that the board’s proposed regulations would create inconsistency to

nurses in these facilities. Mr. Myer also testified that he would not want progress in utilizing automated dispensing machines impeded by the requirements of the proposed regulations.

“Notwithstanding any other provision of law, it is not necessary to include the requirements of 1707.5 if a pharmacist dispenses a medication for a patient in a facility licensed pursuant to Section 1250 of the Health and Safety Code.”

Moreover, CPhA’s Long Term Care Management Counsel recommends additional language as follows with respect to those patients being discharged from specified health care facilities:

“Upon discharge from a facility licensed pursuant to Section 1250 of the Health and Safety Code, a patient may choose not to have his or her medications pursuant to Title 16 Section 1707.5 by signing an opt-out waiver.”

Mr. John Durham of PharMerica Inc. reiterated the comments of Mr. Greg Light and requested that residents in facilities licensed by the Department of Health Services and facilities licensed by the Department of Social Services be exempt from the proposed regulation, as they are caregiver focused..

Dr. Steve Gray representing Kaiser Permanente testified that long-term care or residential facilities not be exempted from the proposed regulation. He added that he is more sympathetic if it is a skilled nursing facility where the Department of Public Health requires certain qualifications of individuals, but that residential care or assisted living – regulated by the Department of Social Services – require lower minimum qualifications. He added that Kaiser’s experience shows that pharmacists and physicians go out to these facilities frequently to resolve problems, in that care is often provided by minimally educated, sometimes limited English proficient personnel, including patient’s family members.

Dr. Steve Gray representing Kaiser Permanente does not support an exemption from the labeling requirements for persons who are being discharged from skilled nursing or assisted living facilities. He testified that these patients essentially are given outpatient prescriptions and that when the patient goes home, they need all of the assistance in understanding and readability that would be provided to any outpatient. He stated such an exemption causes them concern because they see readmissions of patients following discharge from such facilities, because patients get confused.

Mr. Greg Light testified that for patients in the community care licensed facilities, these facilities utilize multi-dose packaging systems. He states that it would be virtually impossible to comply with the board’s proposed labeling requirements.

Mr. Scott R. Huhn, PharmD, of Omnicare, requested that the board consider an exemption to the regulation for pharmacies servicing various health care facilities, such as skilled nursing, intermediate care, psychiatric, assisted living and board/care.

General Comments re: Title VI of the Civil Rights Act of 1964

The board received general comments regarding a patient's right under Title VI of the Civil Rights Act of 1964. These general comments are summarized below but are not responded to as they are either outside the scope of the regulation, do not address any specific text, do not state objection to specific text, or do not comment on the procedures followed by the board. The board does not prescribe requirements regarding what types of funding a pharmacy receives for its products and services (i.e., Medical or other insurers). The board has no jurisdiction to enforce provisions of Title VI of the Civil Rights Act of 1964.

APIAHF states that most pharmacies are recipients of Federal financial assistance and are required to comply with Title VI of the Civil Rights Act of 1964; implementing regulations of which require that recipients of Federal financial assistance must provide meaningful access to their programs, services and activities for LEP persons.

Ms. Deanna Jang of the Asian Pacific Islander American Health Forum (APIAHF) also comments that the proposed regulations do not comply with Title VI of the Civil Rights Act of 1964.

Broad Comments regarding the prescription label (in general)

The NACDS, CPhA and CRA requests that pharmacies be able to provide patients with prescription container information through other means, such as a separate sheet in a larger font.

General Comments re: size of prescription bottles

The NACDS, CPhA and CRA state that chain pharmacies have estimated that many prescriptions currently dispensed in small vials will have to be dispensed in larger vials to accommodate the larger labels. They add that pharmacies will not be able to use the drug manufacturer unit of use containers that are helpful for patients and that patients will likely be dissatisfied with the vials that are several times larger than what they are used to. Further, the NACDS, CPhA and CRA assert that larger container vials will result in shipping, storage and handling problems, with increased costs to pharmacies. (No data or information was provided to the board to indicate current costs to pharmacies or what "increased costs" may represent.)

Ms. Nan Brasmer, California Alliance of Retired American, testified that utilizing a larger prescription bottle to accommodate a label that reflects 12-point font makes sense for many seniors who have difficulty opening small bottles. She testified that a larger label also allows for specific directions for use, which is more useful than utilizing a direction that states "take as directed." These comments were also reflected in the testimony of Ms. Jan Howe, also of CARA.

General Comments re: Auxiliary or Warning Labels; Advertising; Cost; Impact

Mr. Stephen Rosati testified that auxiliary or warning labels should be a minimum of 6-point sans serif typeface. He states that he believes the warning labels are part of the enabling

legislation. He states that auxiliary labels tell you how to utilize your medication and that if a patient can't read how to properly use the medication, that we're back to where we started. Mr. Rosati provided sample containers with mock-up labels utilizing 12-point, 8-point and 6-point typeface. He said the board has 'alternate' language that would require a pharmacy to provide at no less than 12-point font, a separate document with prescription drug information, but that there is no requirement that auxiliary or warning labels utilize a minimum font size. He states that if a separate document is being provided to a patient in a font no less than 12-points, that the same document provide the auxiliary or warning labels in no less than 12-point font typeface.

Mr. Rosati suggested that the board should require that "no form of advertising" should be allowed on the prescription label, prescription container or container top.

With respect to cost, Mr. Rosati stated he spoke with his container manufacturer and he understands that some manufacturers are making changes with the resins for plastics. With that, he states that the minimum bottle was going to jump up one size which may increase it approximately 3 cents per bottle. He states he believes that manufacturers are making shorter, wider bottles to compensate for increased width of a prescription label. Mr. Rosati stated that to comply with the proposed regulations he may incur a one-time cost of approximately \$40 for a new plate, and that if he has a custom plate made, he may incur a one-time cost of approximately \$400.

Ms. Missy Johnson of the California Retailers Association testified that national corporations operate on a very slim margin. She testified to the types of staff and services that are provided in a retail setting.

Ms. Johnson stated that the CRA supported the board's goal of reducing medication errors and developing a standardized patient label; however, she stated that she has significant concerns with the regulatory language.

Ms. Mary Staples of the National Association of Chain Drugstores (NACDS) stated that she would detail the joint letter authored by the California Retailers Association (CRA), the California Pharmacists Association (CPhA), and the National Association of Chain Drugstores (NACDS). (See letter dated January 4, 2010.)

Ms. Lynn Rolston, California Pharmacists Association, testified generally in support of the regulation effort. She stated that the prescription label was only one of the recommendations provided by the original SCR 49 panel. She stated her concern that the board is being overly prescriptive in terms of mandating what the label looks like, and she said that pharmacies would like as much latitude as possible to serve their customers. Ms. Rolston stated pharmacies are sensitive to extra cost. She said many pharmacies may be required to purchase new label stock and have to discard old label stock. She referenced a comment regarding a \$400 strike plate for an independent pharmacist, noting there are 2,000 independents and a number of different systems. She supported prior testimony regarding a phase-in period for implementation. With respect to auxiliary and warning labels, she stated that the board – if they considered these items – would need to define what those items are for clarity.

General Comments re: Language Access

As a California certified Administrative Hearing Interpreter and instructor, Ms. Goodfriend-Koven, City College of San Francisco Health Care Interpreter Certificate Program, states she is acutely aware of the difficulties that many patients have in understanding their prescription drug instructions.

Mr. Anthony Wright, Executive Director of Health Access California, provided information the consumer groups served by Health Access California. He stated that the regulations, as initially proposed, represent a credible start to the implementation of SB 472, which requires the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered prescription drug label on all prescription medication dispensed to patients in California.

Mr. Wright reflected on testimony he heard at the board's October 2009 public hearing – testimony indicating difficulty in implementing the draft regulatory language, and those that spoke in favor, further indicating that in large measure they were already adhering to key features of the draft regulation. Health Access California believes that standardized, readable, language-accessible prescription labels are a vital element in appropriate health care delivery, and they strongly believe the draft regulations should be adopted at the January 2010 Board Meeting.

Ms. Kara Bush of the California Grocers Association commented that while pharmacies are aware of potential for improvements in prescription medication labeling and counseling to improve health literacy and patient safety, physicians, pharmacists, and patients also have responsibilities in ensuring appropriate medication use. Specifically, patients have the responsibility to request information from their physicians, and if they need additional information, from their pharmacists. Ms. Bush states that more evidence is needed on how to make labels more comprehensible yet manageable.

Ms. Bush states that although some research has been conducted on how to improve labels, more analysis is needed to determine what changes can be made to fulfill the statutory requirements without causing such a significant impact on the pharmacies. She states that there is no strong evidence to demonstrate that changing the label, as defined in the proposed regulations, will lead to better adherence, fewer adverse consequences, or better patient outcomes.

Ms. Bush asks that the board collaborate with the CGA in an effort to develop regulations that are cost effective, feasible and practical to implement, and that CGA would be happy to work with the board to develop alternatives to achieve the statutory mandate.

Ms. Doreena Wong of the National Health Law Program (NHeLP) provided background on the organization. She stated that NHeLP believes that the proposed regulations represent a retrenchment from the intent of SB 472 and the board's draft language shared with the public at its July and October 2009 meetings. NHeLP believes that testimony presented to the board

provides critical evidence about the needs of limited-English proficient patients and clearly supported the need for translation of prescription drug labels.

NHeLP does not believe that the proposed regulation reflect the statutory requirement that the board take into consideration the needs of LEP patients. Ms. Wong adds that there are other federal and state requirements and guidelines to ensure linguistic access to LEP patients by pharmacists in various contexts, and provides references to various federal and state statutes, regulations and guidelines, including references to Board of Pharmacy regulations. In addition, NHeLP provided reference materials regarding the need for language assistance services as well as some articles illustrating the existence of technology capable of performing translations into many languages.